



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/598,416

10/06/2006

Stefan Willmann

100717-691 KGB

4318

27384

7590

08/04/2010

Briscoe, Kurt G.

Norris McLaughlin & Marcus, PA

875 Third Avenue, 8th Floor

New York, NY 10022

EXAMINER

NEGIN, RUSSELL SCOTT

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

08/04/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,416	Applicant(s) WILLMANN ET AL.	
	Examiner RUSSELL S. NEGIN	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/23/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Species A-2, B-1, C-2, D-3, E-1, and F-1 in the reply filed on 8 June 2010 is acknowledged. The traversal is on the alleged ground(s) that lack of unities involving species is irrelevant when the species are in dependent claim(s) from an independent claim "characterized by unity of invention;" and applicant further argues that the species in Category A are drawn to the same general inventive concept. The argument with regard to unities of invention and independent claims that are characterized by unity of invention is not persuasive because while it is pertinent to determining lacks of unities between groups, there is no explicit passage in MPEP section 1850 that supports this same assertion for genus/species in lack of unities. Conversely, the fifth paragraph from the bottom of MPEP section 1850 part II teaches that genus/species in lack of unities are relevant when dependent from the same independent claim wherein the independent claim is NOT free of the prior art (and the 35 U.S.C. 103 rejections below demonstrate that the independent claim is NOT free of the prior art). With regard to the argument pertaining to the species of Category A pertaining only to the same general inventive concept, it is determined that only Species A-1 and A-2 are rejoined; absent any support from this assertion, Species A-3 is determined to be drawn to a different inventive concept. Likewise, in Category B, Species B-1, B-7, and B-8 are rejoined because these species are all determined to be drawn to the same inventive concept. Likewise, in Category E, Species E-1 and E-3 are

Art Unit: 1631

rejoined because these species are all determined to be drawn to the same inventive concept.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 are pending in the instant Office action.

Claims 1-10 are examined in the instant Office action.

Information Disclosure Statement

The Information disclosure statement filed on 23 February 2007 has been considered.

Specification

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Specifically, line 15 of page 1 has a hyperlink.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Based upon consideration of all of the relevant factors with respect to the claim as a whole, claim(s) 1-10 are held to claim an abstract idea, and are therefore rejected as ineligible subject matter under 35 U.S.C. 101. The rationale for this finding is explained below.

According to the *Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos* (75 FR 43922 at 43927 (27 July 2010)), factors that weigh against the eligibility of a process include no recitation of a machine or transformation, involvement of the machine is merely tangentially related to the performance of the steps, and the claim is a mere statement of a general concept.

Claims 1-10 are drawn to methods for the controlled dosage of a medicament as a function of time. These methods do not transform (either explicitly or inherently) any particular physical article. While step d of claim 1 controls the dosage device based on simulated results and claim 2 and the preamble of claim 1 recite that the purpose of the method is to determine a dosage of medicament on a subject (animal or human), there is no active step of actually administering a dosage of medicament to any subject in any of the claims. AT MOST, step b of claim 1 theoretically simulates physiology based pharmacokinetic and/or pharmacodynamic properties of a medicament to be administered; this step does not require any empirical administering of any drug. While step d of claim 1 recites a machine in terms of a dosing device, this machine is only tangentially related to the performance of the steps. In other words, the "machine" of

Art Unit: 1631

step d of claim 1 only controls the dosage device, and this controlled dosage device is never recited to be involved in executing the steps a, b, and c of the method.

Additionally, as discussed above, while step b of claim 1 theoretically simulates physiology based pharmacokinetic and/or pharmacodynamic properties of a medicament to be administered, the step never states the need for a computer for such a simulation vs. manually executing the simulation by hand. Furthermore, while claim 10 recites that success of therapy is measured online (i.e. related to a machine), this online measurement of success is not related to any significant method step of the claim; instead, it is insignificant because it only pertains to analyzing results and not to performing the critical steps of generating the required results.

The claims merely recite a general concept of controlling the dosage of a medicament, and not a practical application of such a concept. Consequently, the methods claimed are wholly directed to an abstract idea, and therefore are directed to non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the body to be treated" in lines 8-9. There is insufficient antecedent basis for this limitation in the claim. Claim 1 never recites any body or subject that is or will be treated according to the recited method. For the purpose of examination, it is interpreted that the target profile of step a of claim 1 is of a normal result after treatment from a subject (i.e. the body that is or will be treated).

Claim 2 is indefinite because while the claim recites that "the dosage of the medicament is carried out on humans or animals," and the preamble of claim 1 recites that this independent claim is drawn to determining the controlled dosage of a medicament, there is no step in either claim 1 or earlier in claim 2 requiring administering any dosage of a medicament to any subject. Consequently, as there is no basis for this dosage of a medicament, it is not known which step of claim 1 that claim 2 further limits. For the purpose of further examination, it is interpreted that the target profile in claim 1 is a result of successfully administering a dosage to a subject.

Regarding claim 4, the phrase "(water, fat and protein components)" renders the claim indefinite because it is unclear whether the limitation(s) in this parenthetical phrase are a required part of the claimed invention versus as only exemplary embodiments. See MPEP § 2173.05(d). For the purpose of further examination, it is interpreted that this parenthetical phrase comprises exemplary embodiments.

Regarding claim 5, the phrase "(in the aqueous system or in artificial intestinal fluid)" renders the claim indefinite because it is unclear whether the limitation(s) in this parenthetical phrase are a required part of the claimed invention versus as only exemplary embodiments. See MPEP § 2173.05(d). For the purpose of further

Art Unit: 1631

examination, it is interpreted that this parenthetical phrase comprises exemplary embodiments.

Claim 10 recites the limitation "the therapy" in line 2. There is insufficient antecedent basis for this limitation in the claim. The term "therapy" is not recited earlier in claim 10 or at any point in claim 1. For the purpose of examination, success of the therapy is interpreted to represent the degree of similarity between the target and simulated profiles of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1631

35 U.S.C. 103 Rejection #1:

Claims 1-4 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christopherson et al. [US Patent 5,944,680; issued 31 August 1999] in view of Winokur et al. [US Patent 5,968,932; issued 19 October 1999] in view of Willmann et al. [Biosilico, volume 1, September 2003, pages 121-124; on IDS].

Claim 1 is drawn to a method for the controlled dosage of a medicament as a function of time. The method comprises specifying and indication and substance dependent target profile that indicates a desired effect-time profile. The method also comprises physiology-based pharmacokinetic and/or pharmacodynamic simulating with a time-variable application profile while taking into account individual anatomical and/or physiological parameters of a body to be treated and substance-specific input parameters of the medicament to be administered. The method also comprises iterative adapting of the application profile until the simulated time profile matches the predetermined target profile. The method additionally comprises controlling a dosage device based on the iterative computation.

The document of Christopherson et al. is drawn to a respiratory effort detection method [title]. The method is used to correct breathing patterns of humans with respiratory disorders (focusing on sleep apnea) [abstract, cover figure, and column 1, lines 13-21 of Christopherson et al.]

Specifically, normal (i.e. target) respiration profiles (flow of area through the subject over time) are specified in Figure 2 of Christopherson et al. Figure 4C of Christopherson et al. illustrates a respiration profile of a subject with sleep apnea. To

Art Unit: 1631

correct the profile, the apparatus ("dosage device") illustrated in Figure 5 of Christopherson et al. is implanted into the patient. When the respiratory profile of the subject is abnormal (such as in Figure 4C of Christopherson et al.) column 30, lines 30-35 of Christopherson et al. teach that this device administers a dose of voltage that is optimized over several trials (i.e. iterations) to correct the abnormal respiratory profile to maximize agreement with the normal respiratory profile.

However, Christopherson et al. does not teach use of a medicament (instead, Christopherson et al. uses electric voltages to resolve sleep apnea). Also, Christopherson et al. does not teach using simulations to model a diseased subject using physiology-based pharmacokinetic profiling (instead, Christopherson et al. obtained the diseased respiratory profile empirically).

The document of Winokur et al. alternatively inhibits sleep apnea with the medicament of the pharmaceutical salt of 6-methyl-5-oxo-3-thiomorpholinylcarbonyl-L-histidine-L-prolinamide [title and abstract].

Christopherson et al. and Winokur et al do not teach using simulations to model a diseased subject using physiology-based pharmacokinetic profiling (instead, Christopherson et al. obtained the diseased respiratory profile empirically).

The article of Willmann et al. teaches the simulation software "PK-Sim," a physiologically based pharmacokinetic "whole body" modeling algorithm. Specifically, Figure 1 on page 122 of Willmann et al. illustrates that to determine the effect of a medicine on the (in this case) human body, the human body is computationally decomposed into a series of connected boxes, wherein each box represents an organ

Art Unit: 1631

or bloodpool. Differential equations are used to model the kinetics of the profile of the medicine through the iteratively connected boxes as a function of time using a series of empirically obtained parameters.

With regard to claim 2, the cover figure of Christopherson et al. and Figure 1 of Willmann et al. illustrates that the dosage device and simulation is applicable to humans. Claim 1 of Winokur et al. indicates that their medicament for sleep apnea is applicable to mammals.

With regard to claim 3, column 2, lines 20-30 of Winokur et al. teach intravenous and oral dosages of Montirelin (6-methyl-5-oxo-3-thiomorpholinylcarbonyl-L-histidine-L-prolinamide) to treat sleep apnea. Additionally, column 3, lines 20-40 teach inhalation of Montirelin.

With regard to claim 4, Figure 1 of Christopherson et al. illustrates the volume and composition of a throat and trachea that are normal. Figure 3 of Christopherson et al. illustrates the volume and composition of a throat and trachea that are diseased with sleep apnea. With regard to claims 8-9, the respiratory profiles in Figures 2 and 4 of Christopherson et al. are measured physiologically by the apparatus anatomically positioned in the human in Figure 5 as the subject breathes (real-time).

With regard to claim 7, the device infused into the human in Figure 5 of Christopherson et al. pumps voltage into the human respiration pathway to correct for abnormal respiration profiles.

With regard to claim 10, the therapy in Christopherson et al. is evaluated by measuring pressure through the measurement probe of a pressure sensor (Figure 6 of Christopherson et al.) to determine the signal of intensity of air flow. Additionally, the resultant signal (whether it be normal as in Figure 2 of Christopherson et al. or abnormal as in Figure 4C of Christopherson et al.) controls whether the dosage of voltage is given by the apparatus to clear the pathway.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the implanted device that applied voltages to treat sleep apnea as in Christopherson et al. by use of administering the medicament Montirelin as in Winokur et al. wherein the motivation would have been that the use of the pharmaceutical in Winokur et al. is non-invasive (i.e. no devices need to be implanted- column 2, lines 20-30 of Winokur et al. and column 3, lines 20-40 of Winokur et al. as compared with Figure 5 of Christopherson et al). There would have been a reasonable expectation of success in combining Christopherson et al. with Winokur et al. because both studies pertain to applying optimized dosages (i.e. electricity or chemicals) for treating sleep apnea when abnormal breathing patterns occur.

It would have been further obvious to someone of ordinary skill in the art at the time of the instant invention to modify the invasive and noninvasive approaches of administering dosages in Christopherson et al. and Winokur et al., respectively, by use of the computational simulation for the "whole body" as in Willmann et al. wherein the motivation would have been that computational simulation of dosage performance eliminates the need to administer dosages to a subject- invasively or noninvasively- until optimized conditions have been modeled [Figures 1 and 2 of Willmann et al.]. There would have been a reasonable expectation of success in combining the general study of Willmann et al. to the specific assessment of sleep apnea in Christopherson et al. and Winokur et al. because as the simulations of Willmann et al. are applicable to the "whole body " [title], and the throat and trachea are parts of the body, Willmann et al. provides generally applicable simulated results to the documents of Christopherson et al. and Winokur et al.

35 U.S.C. 103 Rejection #2:

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Christopherson et al. in view of Winokur et al. in view of Willmann et al. as applied to claims 1-4 and 7-10 above, in further view of Sugita et al. [US PG PUB 2003/0175350 A1; published 18 September 2003].

Claim 5 is further limiting accounting for the substance specific parameter of free fraction of the medicament in plasma.

Art Unit: 1631

The documents of Christopherson et al., Winokur et al., and Willmann et al. make obvious methods for determining the controlled dosage of a medicament, as discussed above. The abstract of Winokur et al. teaches use of the drug Montirelin to treat sleep apnea.

The documents of Christopherson et al., Winokur et al., and Willmann et al. do not teach the property of free fraction of the Montirelin in blood plasma.

The document of Sugita et al. teaches preparation and characterization of thyrotropin-releasing hormones and their derivatives [title, abstract]. Paragraph 5 of Sugita et al. teaches that Montirelin is a derivative of thyrotropin-releasing hormones. Paragraph 49 of Sugita et al. teaches the process for measuring blood plasma levels of thyrotropin-releasing hormones and their derivatives.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the empirical and computational determination of controlled dosage of Christopherson et al., Winokur et al., and Willmann et al. by use of the blood plasma measurement techniques for Montirelin in Sugita et al, wherein the motivation would have been that the result of Sugita et al. yields information on how much Montirelin is capable of dissolving in the bloodstream.

35 U.S.C. 103 Rejection #3:

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Christopherson et al. in view of Winokur et al. in view of Willmann et al. as applied to

Art Unit: 1631

claims 1-4 and 7-10 above, in further view of Numerical Modeling [Definition of Numerical Modelling, 2000, The Dictionary of Physical Geography].

Claim 6 is further limiting wherein numerical optimization methods comprise gradient and stochastic methods.

The documents of Christopherson et al., Winokur et al., and Willmann et al. make obvious methods for determining the controlled dosage of a medicament, as discussed above. Figure 1 of Willmann et al. suggests a system of differential equations needed to model the pharmacokinetics of a medicament when administered to the body.

The documents of Christopherson et al., Winokur et al., and Willmann et al. do not teach gradient and stochastic methods for optimizing dosages.

The article on Numerical Modeling teaches that gradients and stochastic analyses forms of techniques used to model differential equations [see definition].

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the empirical and computational determination of controlled dosage of Christopherson et al., Winokur et al., and Willmann et al. by use of the mathematical techniques in Numerical modeling because it is obvious to combine known elements in the prior art to yield a predictable result. In this instance, the stochastic and gradient techniques are alternate techniques used to solve differential equations. There would have been a reasonable expectation of success in combining the techniques of Numerical modeling with the differential equations in the dosage studies of the combination of Christopherson et al., Winokur et al., and Willmann et al.

Art Unit: 1631

because the Numerical modeling taught in the definition is general for any system of differential equations (including the differential equations on Willmann et al.).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Double Patenting Rejection #1:

Claims 1-2, 5-6, and 9-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-7 of copending Application No. 11/917,452. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-2, 5-6, and 9-10 of the instant application are drawn to methods for the controlled dosage of a medicament as a function of time. Claims 2-7 of '452 are drawn more specifically to a device for the time-controlled administration of the anesthetic propofol wherein the embodiments of '452 comprise the embodiments of claims 1-2, 5-6, and 9-10 of the instant application (i.e. target concentration-time profile, a simulated PBPK concentration-time profile, iteratively fitting the simulated PBPK concentration-time profile to the target concentration-time profile, and transferring the result to a dose device). In other words, the embodiments of claims 2-7 of '452 are a species of the embodiments of claims 1-2, 5-6, and 9-10 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Double Patenting Rejection #2:

Claims 1-2 and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-12 and 16 of copending Application No. 11/569,449. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-2 and 6 of the instant application are drawn to methods for the controlled dosage of a medicament as a function of time. Claims 11-12 and 16 of '449 are drawn to a method for determining optimized dosages and transferring the optimized dosage to a dosage device. The steps of '449 encompass the steps of claims 1-2 and 6 of the instant application (i.e. an a resulting/target concentration-time profile, a simulated PBPK concentration-time profile, iteratively optimizing the simulated PBPK concentration-time profile such that there is minimum deviation with the resulting/target profile, and transferring the optimized dosage to a dosage device) plus other limitations. In other words, the embodiments of claims 11-12 and 16 of '449 are a species of the embodiments of claims 1-2 and 6 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices

Art Unit: 1631

published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)).

The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Russell S. Negin/
Examiner, Art Unit 1631
31 July 2010